

**Remarks**

Claim 1 has been canceled without prejudice or disclaimer, and with the understanding that the canceled subject matter may be pursued in a future continuation application. New claims 39 through 83, which have been added, are identical to the claims that appear in the supplemental response after final that was filed in the parent application, 09/562,376. The claims in the subject application should not be interpreted as an abandonment of the claims being pursued in the parent application, which are currently under appeal. The new claims find full support throughout the specification and do not introduce new matter. After entry of this amendment, claims 39 through 83 will be pending.

**1. Rejection under 35 U.S.C. § 102(b)**

Claim 1 is rejected as allegedly being anticipated by U.S. Patent 5,728,393 to Soudant *et al.* ("Soudant"). According to the Examiner, Soudant discloses an anhydrous gel comprising absolute ethanol, hydroxyethyl cellulose, propylene glycol, polyethylene glycol and N-oleoyldihydrosphingosine.

Claim 1 has been canceled. New claims 39 through 83 require the presence of ketoconazole. Soudant does not teach or suggest ketoconazole. For at least this reason, Soudant does not anticipate Applicants' claims 39 through 83. Applicants therefore respectfully request that this rejection be withdrawn.

**2. Rejection under 35 U.S.C. § 103(a)**

Claim 1 is rejected as allegedly being obvious over U.S. Patent 5,993,787 to Sun *et al.* ("Sun"). According to the Examiner, Sun discloses anhydrous topical preparations comprising (I) propylene carbonate; (II) one or more alcohols and/or glycols, including ethanol, isopropanol, propylene glycol, polyethylene glycol, *etc.*, and (III) a therapeutically or cosmetically active ingredient. The Examiner acknowledges that Sun does not specifically disclose an anhydrous composition with the particular alcohol + glycol combination as claimed by Applicants. However, the Examiner asserts that it would have been obvious to a person of ordinary skill in the art to prepare an anhydrous composition comprising, for example, ethanol and polyethylene glycol, because Sun (1) broadly teaches a genus of anhydrous topical compositions containing components that fall within the scope of Applicants' claims; (2) teaches that one or more of the disclosed alcohols and/or glycols may be used in the anhydrous topical compositions; (3) specifically exemplifies anhydrous topical compositions wherein multiple alcohols

and/or glycols are disclosed; and (4) specifically discloses ethanol, isopropanol, propylene glycol and polyethylene glycol as components useful in the described compositions.

Claim 1 has been canceled. Regarding new claims 39 through 83, Applicants respectfully disagree with any perceived applicability of Sun to Applicants' claimed subject matter. As one reason, Sun clearly states that propylene carbonate is an essential component in the described compositions. "The instant anhydrous formulations employ propylene carbonate as the primary solvent for the active ingredients because of its considerable solubilization properties" (col. 5, lines 32-34). Additional disclosure in Sun of the critical nature of propylene carbonate may be found, for example, in the statement that "[i]n the event one or more active ingredients are provided, the propylene carbonate functions as a primary solvent and the alcohol and/or polyol functions as a secondary solvent for such ingredients" (col. 5, lines 41-44).

In contrast, none of Applicants' claims specifically recite propylene carbonate as a component of the claimed anhydrous compositions, which include ketoconazole as an active ingredient. 35 U.S.C. § 112 requires that an applicant's claims must particularly point out and distinctly claim the subject matter which the applicant regards as his invention. The lack of inclusion of propylene carbonate in any of Applicants' claims indicates that propylene carbonate, unlike its presence in the Sun compositions, is not essential to the operability of Applicants' invention.

Furthermore, Applicants' specification does not even disclose propylene carbonate as a suitable component of the described compositions. M.P.E.P. § 2141.02 requires that a prior art reference must be considered as a whole, including portions that would lead away from the claimed invention. After reading Sun, a person of ordinary skill in the art would clearly have no reasonable expectation of success in preparing a composition that did not include propylene carbonate as a component. For at least this reason, Sun cannot therefore render obvious Applicants' claimed anhydrous compositions and Applicants respectfully request that this rejection be withdrawn.

### 3. Double Patenting

#### A. **U.S. Patent 6,238,683**

Claim 1 is rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claim 1 of U.S. Patent 6,238,683 ("the '683 patent"). The Examiner asserts that claim 1 of the '683 patent is within the scope of Applicants' claim 1 because claim 1 of the '683 patent

recites an anhydrous composition comprising propylene glycol, PEG, glycerin, an anhydrous vehicle and the medicaments ketoconazole and desonide.

Claim 1 has been cancelled. Applicants intend to file a Terminal Disclaimer over U.S. Patent 6,238,683 once allowable claims in the subject application have been identified.

**B. U.S. Patent Application No. 09/562,376**

Claim 1 is provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claim 48 of copending Application No. 09/562,376 ("the '376 application"). The Examiner asserts that claim 48 of the '376 application claims an anhydrous composition comprising an anhydrous vehicle, propylene glycol, PEG, glycerin and at least one azole antifungal agent.

Claim 1 has been canceled. Applicants intend to cancel the claims pending in the '376 application if the claims in the subject application are found to be in a condition for allowance.


**4. Conclusion**

The foregoing amendments and remarks are being made to place the application in a condition for allowance. Applicant respectfully requests reconsideration and the timely allowance of the pending claims. Should the Examiner find that an interview would be helpful to further prosecution of this application, he is invited to telephone the undersigned at his convenience.

**Except** for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: August 1, 2005  
Morgan, Lewis & Bockius LLP  
Customer No. 09629  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Tel: 202-739-3000  
Fax: 202-739-3001

Respectfully submitted  
**Morgan, Lewis & Bockius LLP**

  
\_\_\_\_\_  
Gregory T. Howen  
Registration No. 46,882  
Direct: 202-739-5915